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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/645,970 | 08/22/2003 | Morteza Naghavi | D8562-16 | 8386 |
| 25397 | 7590 | 08/23/2007 | | |
| DUANE MORRIS LLP 3200 SOUTHWEST FREEWAY SUITE 3150 HOUSTON, TX 77027 | | | EXAMINER LAURITZEN, AMANDA L | |
| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/645,970 | Applicant(s) NAGHAVI ET AL. | |
| | Examiner Amanda L. Lauritzen | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. The following statement,

It is emphasized that this abstract is provided to comply with the rules requiring an abstract which will allow a searcher or other reader to quickly ascertain the subject matter of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims

is not appropriate as it is clearly not related to the technical disclosure of the invention. Note that the examiner understands this to be true without being said. It is suggested that the above statement be cancelled.

Rule 130, 131 or 132 Affidavit

2. Acknowledgement is made of the declaration under 37 CFR 1.131 to disqualify Iatrou et al. (US 2004/0136491) as prior art under 35 U.S.C. 102(e) and/or 103(a). New grounds for rejection are presented herein.

Claim Objections

3. Objection to claims 30, 32 and 33 regarding improper dependency are withdrawn in view of the amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 3737

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-14, 17-28 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu (US 6,233,304) as evidenced by Kaufman et al. (US 2003/0095693).

Hu et al. disclose a method for detecting coronary artery calcification (CAC) by multi-slice helical reconstruction and/or electron beam computed tomography in a system with arrayed detectors (col. 1, lines 13-15; 42-64). A distribution of calcification is acquired in the form of an attenuation transmission profile (col. 1, lines 19-21), with visualization of data giving rise to mapping sections of arteries or vessels of interest. While it is understood that these tests are used for diagnostic purposes, the method of Hu et al. is not expressly correlated to disease risk assessment; however, Kaufman et al. teach that calcium scoring is generally used for assessing risk of coronary heart disease [0004-5]. System components are understood to include data storage and analysis components.

The method of Hu et al. includes calculation of x-ray attenuation coefficients in the form of CT numbers that are used in threshold comparison (col. 4, lines 15-36, in which a threshold of 130 HU is selected). The calcium score weighting algorithm for slice spacing correction would include determining changes in calcification density. Hu et al. further disclose plaque density assessment.

Regarding claim 11, Hu et al. do not explicitly disclose relating calcification densities to an outcome of a lesion; however, Kaufman et al. teach that motion artifact will have an effect on the calcification score and that this motion is related to a lesion [0008]. It would have been obvious to one of ordinary skill in the art at the time of invention to relate calcium scores to an outcome of a lesion in the form of blurring and/or motion artifact for assessing resolution and

equipment calibration as taught by Kaufman et al. The image data are presented as pixel density scores and when displayed comprise a transmission profile or map (col. 4, lines 3-55). The progression of plaque is visible from pixel to pixel or from pixel densities across selected regions (col. 4, lines 3-5; 36-51). Regarding claim 15, it is understood that these scores and/or images are used for diagnostic purposes, but the method of Hu et al. is not expressly correlated to disease risk assessment; however, Kaufman et al. teach that calcium scoring is generally used for assessing risk of coronary heart disease [0004-5].

Regarding claims 12, 13, 27 and 28, both Kaufman and Hu et al. disclose statistical calculation(s), including at least calculation of an average and a range in determination of a peak value [Kaufman 0082]. Visualizing the data will result in a map of sections of vessels statistical distribution of calcification of each of a plurality of sections or regions (Hu et al., col. 4, in which a distribution of density scores of pixel values of regions of interest is obtained).

5. Claims 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu and Kaufman et al., as applied to claims 14 and 28 above, further in view of O'Brien et al. (US 2004/0057955).

Hu in view of Kaufman, as discussed above, includes all features of the invention as substantially claimed and while it can be inferred that a progression of plaque can be visualized in the data, it is not expressly disclosed that progression of plaque is determined; however, O'Brien discloses a method for treating calcific aortic valve disease [0003-4], including monitoring the calcification and analysis of the progression of plaque. O'Brien further discloses that statistical analyses were done on data obtained from scans wherein the progression of the plaque was observed to evaluate the relationship between progression of plaque and

Art Unit: 3737

cardiovascular risk factors [0085-6]. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Iatrou in light of the teachings in the reference by O'Brien to include determination of progression of plaque to better characterize risk factors for cardiovascular disease.

6. Claim 16 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu, Kaufman and O'Brien et al., as applied to claim 15 above, further in view of Rather et al. (US 6,385,474).

Hu in view of Kaufman and O'Brien, as discussed above, substantially disclose all features of the invention as claimed. While Hu et al. disclose categorizing regions according to calcification scores, neither Hu nor Kaufman explicitly disclose categorizing an area of abrupt change in elasticity as a high-risk region. Rather also discloses a method and apparatus for detection and characterization of medical pathologies, such as calcifications, and further teaches studying density and elasticity of the tissue [0013] in which microcalcifications and tissue elasticity are identified [0025]. Regions where there are abrupt changes re identified and each region is classified according to determined criterion [0087]. It would therefore have been obvious to one of ordinary skill in the art at the time of invention to modify that disclosed by Hu in view of Kaufman and O'Brien in light of the teachings of Rather to include ascertaining regions of abrupt changes which assists in the identification of microcalcifications and tissue elasticity which signal pathology such as cancer or calcified plaque.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the


Art Unit: 3737

examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ALL
8/20/2007


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